UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

THIS DOCUMENT RELATES TO ALL CASES

HON. RENÉE MARIE BUMB

PLAINTIFFS' REPLY BRIEF IN FURTHER SUPPORT OF REQUEST TO PRECLUDE THE TRIAL TESTIMONY OF MAGGIE KONG AND JINSHENG LIN

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INTRODUCTION

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The Parties met and conferred on the proper custodians in this case in the fall of 2019, which included the representation from ZHP that they had identified the necessary custodians, and the Court finalized those eighty-one custodians on December 23, 2019. (ECF 328, p. 19-21). A year later, the parties met and conferred on the proper deponents in this case, and the Court finalized those eighteen deponents on December 31, 2020, including Baohua Chen. (ECF 704). At no time during these meet and confers did ZHP offer Maggie Kong or Jinsheng Lin as custodians or deponents relevant to this case. Valsartan fact discovery ended on June 1, 2021. (ECF 863, p. 1; ECF 2476, p. 1).

On February 22, 2024, two and half years after the close of discovery and weeks before the March 18, 2024 trial date, ZHP informed Plaintiffs that it intended to call both Maggie Kong and Jinsheng Lin as witnesses. (Ex. 1). ZHP has never provided any justification for its failure to identify either witness as a custodian.

As the Court is well aware, both witnesses are tied to the years-long discovery dispute regarding Baohua Chen's deposition and the drastically deficient document production regarding the July 27, 2017 email. To be clear, Maggie Kong was Baohua Chen's Chief of Staff from late 2017 through the relevant time period, and Jinsheng Lin is the author of the July 27, 2017 email.

¹ All exhibits are attached to the accompanying Certification of Adam M. Slater.

In its initial decision granting Plaintiffs' application for Rule 37 sanctions, the Court found "ZHP's conduct appears to be sufficiently self-serving to warrant a finding of bad faith under the *Poulis* test." (ECF 2712, p. 31, 32-33 (emphasis added)). If it allows ZHP to call Maggie Kong and Jinsheng Lin to testify at trial, the Court will provide ZHP a potential last second end run around the sanctions for ZHP's refusal to produce Baohua Chen and the full set of documents related to the July 27, 2017 email, greatly prejudicing Plaintiffs.

Based on the prior representations about Maggie Kong's lack of substantive involvement in or knowledge about any key area of the case, and the glaring inadequacy of Jinsheng Lin's custodial file, these are witnesses who should not be injected into this trial. During the September 9, 2024 hearing, Judge Bumb heard brief argument and stated, "They don't really seem to be adding anything to the case." (9/09/2024 Tr. 169:15-16). Judge Bumb then referred the issue to Judge Vanaskie, noting, "But my preliminary view is, is that if somehow the defendants lulled the plaintiffs or misled them or whatever, they're not going to profit from that." (*Id.* at 172:20-25). The record supports Judge Bumb's preliminary view, as that is exactly what is happening here.

As a result of ZHP unjustified failure to disclose Maggie Kong and Jinsheng Lin as relevant custodians or proper deponents as well as ZHP's bad faith in failing to comply with discovery orders related to what these witnesses may be expected to testify about (no adequate proffer has been made), the Court should bar both Maggie Kong and Jinsheng Lin from testifying at this or any future valsartan trial.

I. Maggie Kong Should Not Be Permitted to Testify.

As the Court is well aware, ZHP repeatedly ignored the Court's numerous orders to produce Maggie Kong's custodial file. (*See, e.g.*, ECF 2712; Pls.' 6/17/2024 Br. in Opp. to ZHP's Objs. to and Mot. to Reverse SMO 98, p. 6-7 (Redacted at ECF 2750)). To that end, ZHP insisted:

Of great concern to the ZHP Parties, Plaintiffs have stated in correspondence and in its submissions to the Court, that the Court has ordered the custodial file of Maggie Kong to be produced when, as the Court is well aware, *there is no such order*. Plaintiffs have failed to cite any such order on the docket, and have instead cited this Court's instruction to the parties that Ms. Kong's custodial file be *collected*, not produced. As even the Court hearing transcripts cited by Plaintiffs make clear, the Court permitted the ZHP Parties to assert their objections on proportionality grounds in this brief, in response to Plaintiffs' motion to compel. *See* Ex. M, 5/12/2021 Tr. 32:15-33:1; and Ex. N, 6/25/21Tr. 30:15-17.

As set forth in the ZHP Parties' prior objections, Ms. Kong is the Chief of Staff to the President of ZHP, Baohua Chen; and she did not join ZHP until late 2017, several years after many of the events at issue in this case. See Dkt. 1237 at 6-7. As a member of the President's staff, she has no direct role in the development, manufacturing, testing or sale of valsartan, nor does she have any regulatory responsibilities at ZHP. Id. Plaintiffs have indicated that their primary goal in collecting Ms. Kong's custodial file is to locate the dates and times of certain meetings involving Mr. Chen; however, the ZHP Parties have confirmed that Ms. Kong does not keep a hardcopy

calendar, and the ZHP Parties' production to date demonstrates that calendaring software is rarely, if ever, used among ZHP's employees, including Ms. Kong. See, e.g., Exs. C, A, and B, Excerpts of 4-22-21 Min Li Deposition at 593:23 – 594:19; 5-4-21 Linda Lin Deposition at 16:15 – 17:13; and 5-27-21 Jun Du Deposition at 85:18 – 86:8, respectively. Further, the Court has already ordered, and ZHP has produced, the files of Baohua Chen, and any responsive information in Ms. Kong's documents is likely to be duplicative of the information produced from Mr. Chen's files. See Arconic Inc. v. Novelis Inc., No. 17-1434, 2019 WL 5802365, at *20 (W.D. Pa. Sept. 6, 2019) (denying request to add custodian because employee "was working at the direction of" an existing custodian).

In addition, because the ZHP Parties do not have a general counsel, Ms. Kong serves as the primary contact with the attorneys; accordingly, responsive Parties' documents within her custodial file contain privileged information, and, for reasons set forth below, a detailed review of her custodial file would therefore be unduly burdensome. Id. Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and *proportional* to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit."). After collecting Ms. Kong's custodial file, applying the courtordered search terms rendered 37,579 document hits, inclusive of families; of that number, 16,339 documents, inclusive of families, were hits for privilege terms. Accordingly, more than 43% of the documents at issue are likely to be privileged.

In light of the testimony of ZHP's witnesses that the information Plaintiffs claim they are seeking (i.e., calendar

and meeting invitations) does not exist in Ms. Kong's custodial file; Plaintiffs' failure to articulate what unique information they are seeking from Ms. Kong that has not been captured by Mr. Chen's production of documents; and the burden of reviewing the extraordinarily high number of privileged documents in Ms. Kong's files, it is disproportionate to the needs of this case to compel the ZHP Parties to review and produce Ms. Kong's custodial file. Accordingly, Plaintiffs' request should be denied.

(ECF 1485 (unitalicized bolding added)).

Thus, ZHP represented that Ms. Kong will not have relevant factual knowledge. Now, without any detailed proffer, ZHP seeks to have her testify. ZHP's representations make it clear that Maggie Kong has nothing to do with this case and that, at most, she would potentially try to offer testimony to undercut or justify Mr. Chen's failure to comply with the Order requiring his deposition. This would greatly prejudice Plaintiffs.

Moreover, Maggie Kong's custodial file is still woefully incomplete, despite ZHP's piecemeal productions. At the time of Plaintiffs' initial Rule 37 motion, ZHP had not produced any part of Maggie Kong's custodial file. ZHP began to slowly produce parts of that file on February 2, 2022. The production is obviously inadequate. This begins with the same black hole as with Baohua Chen's file, no documents between May 21, 2018, and June 15, 2018, despite the interaction with Novartis and need to notify the FDA and its customers during that time period. As of the date of defense counsel Richard Bernardo's October 21, 2022

certification, her file had a scant 1,240 documents. Only 65 of those documents predated Novartis' discovery of the nitrosamine contamination, and 33 of those documents are unhelpful slip sheets stating "Withheld – Other Product(s)." When the irbesartan-specific productions are included, her file has 158 documents before June 15, 2018, with 36 of those being worthless slip sheets stating "Withheld – Other Product(s)." And her custodial file still has a gap between May 24, 2018, and June 15, 2018.²

Plaintiffs explained the significance of these gaps in their June 17, 2024 brief. (P. 19-23 (Redacted at ECF 2750)). In short, the time period between May 21 to June 15, 2018, is when Novartis started questioning ZHP about the unknown peaks in its valsartan and ultimately discovered the NDMA that ZHP had known about since at least July 27, 2017. (*Id.*).

ZHP now claims Maggie Kong will explain why ZHP acted reasonably in waiting until July 13, 2018 to recall its valsartan. (ECF 2855, p. 9-10). The record does not support her ability to offer this testimony because she had no regulatory responsibilities (this is a regulatory issue), was not involved with ZHP's communications with Novartis, and she did not even attend ZHP's initial meeting with the FDA that led to the recall. (PRINSTONOOOO00003 (Ex. 2)). As ZHP

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² Her only two documents during the last week of May 2018 are the same ones as in Baohua Chen's file.

explicitly said in opposition to producing Maggie Kong's custodial file: "As a member of the President's staff, she has no direct role in the development, manufacturing, testing or sale of valsartan, nor does she have any regulatory responsibilities at ZHP." (ECF 1485). The reasonableness of ZHP's timing of the recall falls squarely within ZHP's "regulatory responsibilities." ZHP has already notified Plaintiffs that Linda Lin, ZHP's Director of Regulatory Affairs who reports directly to Baohua Chen, is coming to testify/available to testify live at trial. (Ex. 3).³ Allowing Maggie Kong to opine on these issues despite having no personal involvement, as if she is an affirmative corporate representative (which is not permitted), and without adequate production of her custodial file, would greatly prejudice Plaintiffs.

In sum, Judge Bumb was right that Maggie Kong does not "really seem to be adding anything to the case." (9/09/2024 Tr. 169:15-16). And Judge Bumb was also correct that ZHP "lulled the plaintiffs or misled them," so they should not "profit from that," especially when the proffered witness is such a clear stand in for the company's CEO, who evaded his deposition in bad faith. Any other result would greatly prejudice Plaintiffs.

If Maggie Kong is allowed to testify, defense counsel should be required to

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³ Plaintiffs also note that Baohua Chen was the head of ZHP's valsartan recall team. (ZHP00494052 (Ex. 4)). Maggie Kong is not a member of this team, but Jucai Ge, another witness ZHP plans to call live, is a member.

make a detailed proffer satisfying the Court that her testimony would be fair and fit the issues in the case, and she must be limited to her very narrow personal knowledge of the facts relevant to this case, as supported by her limited custodial file, and cannot be allowed to address issues on behalf of Baohua Chen. (See ECF 2810, p. 2 (amending the jury instruction to remove ZHP's ability to relitigate Baohua Chen's refusal to sit for his deposition)).

Jinsheng Lin Should Not Be Permitted to Testify. II.

ZHP concealed Jinsheng Lin's significance in this litigation until the sole copy of the July 27, 2017 email was uncovered in Chinese, with its incorrect metadata just before Min Li's 30(b)(6) deposition. Based on the circumstances, it is apparent that it was only produced due to the document having been copied off of Min Li's damaged computer and slipping through to Plaintiffs. The time to offer Jinsheng Lin as a custodian, deponent, and witness in the case ended on June 1, 2021.

Jinsheng Lin is presumably intended to testify to deny the meaning or import of the July 27, 2017 email, and if there is any other purpose, that proffer should have been made. The factual record contains no credible evidence disputing Plaintiffs' "understanding" or "interpretation" of the material parts of the email comparing a nitrosamine impurity seen in Irbesartan to the NDMA found in valsartan, with a root cause of the quenching with sodium nitrite, and stating that this is a problem in the manufacture of sartans across the board—all of which was

100% accurate. 30(b)(6) witness Min Li clearly testified to what the email said, which is consistent with ZHP's own translation. (Ex. 5; Min Li 4/20/2021 Dep. 82:11-12, 87:19-88:7, 88:13-89:18 (Ex. 6))). Even Jucai Ge, who is going to testify in ZHP's case, testified that this is what the email stated. (Jucai Ge 4/29/2021 Dep. Tr. 258:17-259:2 (Ex. 7); Jucai Ge 5/26/2022 Dep. Tr. 83:7-84:7 (confirming "that was the words that said so on this page") (Ex. 8)). Jinsheng Lin should not be permitted to contradict sworn testimony from a 30(b)(6) witness, his boss Min Li, thus undercutting the purpose and binding nature of admissions from a corporate representative.

Additionally, the rationale and purpose of the Court's Rule 37 sanctions regarding the missing native copies of the July 27, 2017 email and the related irbesartan investigation report would be undercut if ZHP were allowed to bring Jinsheng Lin to deny the obvious meaning of the key parts of his email. This is especially true where Plaintiffs have never been provided large chunks of Dr. Lin's custodial file, including the documents underlying his knowledge that there was NDMA in valsartan caused by the sodium nitrite quenching and that this was a problem across sartans. As the Court is aware, the July 27, 2017 email was not produced in its native version, was not found in Jinsheng Lin's or any custodial file other than Min Li's, and neither he nor anyone else was listed as a duplicate custodian. (ECF 2712, 2778, 2810). The production is woefully and prejudicially

inadequate.

ZHP misleadingly attempts to refute the fact that Jinsheng Lin's custodial file contains only one document before December 2017. (ECF 2855, p. 5). Throughout this litigation and the years of discovery disputes, the Parties have assessed custodial files using the "Family Date," which is the metadata field showing when each document was preserved; for example, if a document is only produced as an attachment to an email, then its family date is the date of the email, as it was not preserved independently. The earliest Family Date in Jinsheng Lin's custodial file is December 7, 2017. The custodial file has one undated document, which shows a date of July 24, 2017. (ZHP02710344 (Ex. 9)). Thus, Jinsheng Lin's custodial file has only one document independently preserved from before December 2017. Any other documents from before December 2017 are only preserved due to their attachment to later emails or similar circumstances. Plaintiffs would be greatly prejudiced if Jinsheng Lin were allowed to testify regarding the meaning of the July 27, 2017 email without his complete custodial file for that time period and earlier including all documents regarding his evaluation of impurities in valsartan, irbesartan, and losartan. How can Plaintiffs adequately question this witness where ZHP is using the inadequate production as both a sword and a shield at this point.

The prejudice of allowing his testimony in the face of the obviously inadequate productions, compounded by the prejudice of confusing the jury by

allowing ZHP to present a fact witness to refute the binding 30(b)(6) testimony of Min Li confirming the meaning of the email, makes clear that allowing the testimony would greatly prejudice Plaintiffs and confuse the jury.

ZHP self-righteously ignores its bad conduct throughout the litigation and cites a series of cases attempting to show it "has a right to present its case through the witnesses it chooses." (ECF 2855, p. 3). However, those cases did not involve the level of bad faith and prejudice explained above. See Cassell v. SkyWest, Inc., 654 F. Supp. 3d 1222, 1240 (D. Utah 2023) (rejecting a "speculative" motion to exclude "cumulative" and "prejudicial" trial testimony of a witness who was deposed, and did not concern the issues raised here); Lewis v. Sw. Airlines Co., No. 16-cv-00749-JCS, 2016 WL 3091998, at *4 (N.D. Cal. June 2, 2016) (addressing a motion to transfer venue, not exclude a witness from testifying on the grounds at issue here); ABB Air Preheater, Inc. v. Regenerative Env't Equip. Co., 167 F.R.D. 668, 671 (D.N.J. 1996) (declining to exclude expert testimony absent a showing of bad faith); DiFlorio v. Nabisco Biscuit Co., No. CIV. A. 95-0089, 1995 WL 710592, at *2 (E.D. Pa. Nov. 13, 1995) (same); Newman v. GHS Osteopathic, Inc., 60 F.3d 153, 156 (3d Cir. 1995) (addressing "harmless violations" of Rule 26 and finding no "bad faith"); Carnathan v. Ohio Nat'l Life Ins. Co., No. 1:06-CV-999, 2008 WL 4000392, at *2 (M.D. Pa. Aug. 25, 2008) (same with respect to "harmless"); Mosaid Techs. Inc. v. Samsung Elecs. Co., 348 F. Supp. 2d 332, 338 & n.11 (D.N.J. 2004)

(not addressing a request to exclude a witness or evidence); *Borrell v. Bloomsburg Univ.*, No. 3:CV-12-2123, 2015 WL 3613246, at *5-6 (M.D. Pa. June 8, 2015) (finding no "bad faith"); *Jama v. Esmor Corr. Servs., Inc.*, No. 97-3093(DRD), 2007 WL 1847385, at *47-49 (D.N.J. June 25, 2007) (denying a motion to exclude expert testimony over lost drafts of expert reports and related documents); *Masterank Wax, Inc. v. RFC Container, LLC*, No. 19-12245 (KMW/MJS), 2022 WL 19927891, at *8 (D.N.J. Aug. 30, 2022) (denying a motion to exclude evidence because the movant could not establish bad faith); *Washington v. Vogel*, 880 F. Supp. 1534, 1536 (M.D. Fla. 1995) (denying a motion to exclude testimony from a deposed witness that would not result in any prejudice).

Cases involving the type of bad faith and prejudice found here excluded the evidence at issue. *Mercedes Benz USA LLC v. Coast Auto. Grp. Ltd.*, No. CIV.A. 99-3121 (WHW), 2008 WL 4378294, at *4 (D.N.J. Sept. 23, 2008) ("Coast offers no reasonable explanation for its failure to disclose its calculation of damages. At worst, Coast's failure to disclose was in bad faith, at best, it was a wilful strategic decision. In either case, Coast's actions demonstrate that it is not fundamentally unfair to exclude Coast's evidence of damages."), *aff'd sub nom.*, 362 F. App'x 332 (3d Cir. 2010); *Aetna Inc. v. Mednax, Inc.*, No. CV 18-2217, 2021 WL 949454, at *4-7 (E.D. Pa. Mar. 12, 2021); *Kimmel v. Massachusetts Bay Ins. Co.*, No. 21-12743 (CPO)(EAP), 2023 WL 8714336, at *7-12 (D.N.J. Dec. 15, 2023); *Sabol v. Allstate*

Prop. & Cas. Ins. Co., 309 F.R.D. 282, 287 (M.D. Pa. 2015); Bouder v. Prudential Fin., Inc., No. CIV.A.06-4359(DMC), 2010 WL 2026707, at *5 (D.N.J. May 21, 2010); Brooks v. Price, 121 F. App'x 961, 965-66 (3d Cir. 2005) ("We find no abuse of discretion on the part of the District Court in deciding that the exclusion of testimony from Dr. Hameli was the only reasonable way to avoid the prejudice occasioned by Brooks' conduct."); Nicholas v. Pennsylvania State Univ., 227 F.3d 133, 148 (3d Cir. 2000); Martin v. Hudson Farm Club, Inc., No. CV 18-02511, 2021 WL 6265499, at *6-7 (D.N.J. Dec. 31, 2021); Gautier-James v. Hovensa, L.L.C., No. 1:06-CV-00106, 2011 WL 4500153, at *9 (D.V.I. Sept. 27, 2011); In re TMI Litig., 193 F.3d 613, 722 (3d Cir. 1999), amended elsewhere, 199 F.3d 158 (3d Cir. 2000); Gutierrez v. Pell, No. CV 20-6101, 2022 WL 1110593, at *2-3 (E.D. Pa. Apr. 13, 2022) ("The timing of the production of the reports also raises the specter of bad faith."); Dandy v. Ethicon Women's Health & Urology, 579 F. Supp. 3d 625, 632 (D.N.J. 2022); Orr v. Weeks Marine, Inc., No. CV 04-3381 (HAA), 2006 WL 8457613, at *5 (D.N.J. Sept. 18, 2006) ("Weeks persuasively argues that Orr's failure to disclose was not an isolated or minor mishap, but a continuing failure that could reasonably be termed wilfulness at best and bad faith at worst," so "this Court concludes that the violation complained of here is not harmless to Defendant Weeks. As a result, the statements of Posner and Taylor may not be considered in addressing the partial summary judgment motion regarding seaworthiness."); Juice Ent., LLC

v. Live Nation Ent., Inc., No. CV 11-07318, 2022 WL 2803169, at *4 (D.N.J. July 18, 2022); Fillichio v. Toms River Police Dep't, No. CV 19-575 (ZNQ)(DEA), 2022 WL 959278, at *3 (D.N.J. Mar. 25, 2022) ("[T]he prejudice here is not a matter of mere delay"); Mall Chevrolet, Inc. v. Gen. Motors LLC, No. CV 18-15077-JRP-KMW, 2021 WL 426193, at *16 (D.N.J. Feb. 8, 2021); Zarour v. Am. Sec. Ins. Co., No. CIV.A. 13-6384 FLW, 2015 WL 5167164, at *5 (D.N.J. Sept. 3, 2015); Franco v. Connecticut Gen. Life Ins. Co., No. CIV.A. 07-6039 SRC, 2013 WL 5934539, at *2 (D.N.J. Nov. 1, 2013) ("Despite the extreme untimeliness of the new reports, Plaintiffs shockingly take the position that Defendants are not prejudiced because no trial date has been set, and that besides, "even if it could be said that Defendants are somehow 'prejudiced' by consideration of the Foreman Report and the Cohen Declaration, it is clear that any such alleged prejudice is easily curable" by a reopening of discovery."); Roberts v. United States, No. CIV.A. 09-6212 WJM, 2012 WL 2374656, at *6 (D.N.J. June 22, 2012); Steele v. Aramark Corp., No. CIV. 09-4340 JBS/JS, 2012 WL 1067879, at *8 (D.N.J. Mar. 29, 2012) ("The Plaintiffs have not offered any explanation for their failure to disclose this crucial allegation of fact prior to the conclusion of fact discovery; and the disclosure of this fact after the weaknesses of Plaintiffs' case became apparent and Plaintiffs retained new counsel is suggestive of bad faith."), rev. on recon. in other part, No. CIV. 09-4340 JBS/JS, 2012 WL 4103875 (D.N.J. Sept. 17, 2012), rev'd on other part but aff'd on this issue,

535 F. App'x 137 (3d Cir. 2013). These cases support the exclusion of the testimony of both Maggie Kong and Jinsheng Lin.

It is also worth noting, "The party who has failed to disclose information bears the burden to show that the non-disclosure was substantially justified or is harmless." *Bouder*, 2010 WL 2026707, at *3; *Martin*, 2021 WL 6265499, at *6. Here, ZHP has supplied no justification for its failure to disclose Maggie Kong and Jinsheng Lin as custodians and deponents during the 2019 and 2020 meet and confers, and it has repeatedly deflected its failure to produce their full custodial files, even in the briefing on this very issue, instead of providing any concrete explanation or justification for the patently missing documents. Of course, this is not surprising given the Court's prior finding of bad faith with respect to discovery issues central to this case.

CONCLUSION

For the foregoing reasons, the Court should preclude the trial testimony of Maggie Kong and Jinsheng Lin.

Dated: September 27, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2024, I electronically filed this brief and accompanying certification with the Clerk of the Court using CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL. In addition, I hereby certify that a copy of these documents will be served contemporaneous to filing via email on the Special Master and Jessica Davidson at Jessica. Davidson@skadden.com.

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By: /s/ Adam M. Slater

Dated: September 27, 2024